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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/992,491   | 11/21/2001  | Gary S. Hahn         | Sensory 0003.CON3   | 9928             |
| 36032  | 7590        | 11/30/2006           | EXAMINER            |                  |
| THE GRIFFITH LAW FIRM, A P.C.<br>991 C Lomas Santa Fe Drive<br>Suite 450<br>Solana Beach, CA 92075 |             |                      | YU, GINA C          |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1617                |                  |

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |  |
|------------------------------|-----------------|--------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |  |
|                              | 09/992,491      | HAHN ET AL.  |  |
|                              | Examiner        | Art Unit     |  |
|                              | Gina C. Yu      | 1617         |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on August 28, 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-34, 36, 38-54, 56 and 62-77 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4-18, 20-25, 28-32, 41, 46-54, 56, 62-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 26, 27, 33, 34, 36, 38, 42-45 and 66-77 is/are rejected.
- 7) ☒ Claim(s) 39 and 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign\* priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. <u>20060829</u>                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/13/2003</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 29, 2006 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 3, 26, 27, 33, 34, 36, 38, 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bristow et al. (EP 0346957) ("Bristow") as evidenced by Poisoning & Drug Overdoes (2004).**

Claim 1 is directed toward a composition comprising 0.5-10% aqueous soluble divalent strontium cation and a suitable topical vehicle. The phrase "for reducing skin irritation in animals" is a preamble which denotes the intended use or purpose of the present invention. No patentable weight is afforded to this recitation since the phrase does not render any structural limitation to the claimed composition. See MPEP § 2111.02.

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Claim 65 is directed toward a composition comprising a non-strontium active ingredient, a salt comprising aqueous-soluble divalent strontium cation; and a suitable topical formulation vehicle. The phrase "for effecting primary activity of the topical formulation" and "with the proviso that the topical formulation is not a dentifrice" denote the intended use of the claimed invention. Thus no patentable weight is given to these phrases.

Bristow discloses a toothpaste composition for sensitive teeth, comprising 3 % of strontium acetate, a surfactant and an emulsifier (sodium lauryl sulphates), a nonionic surfactant and emulsifier (sorbitol syrup), thickener (sodium carboxymethylcellulose), preservatives (formalin), an active agent (sodium monofluorophosphate and hydroxyapatite), and antibiotic (chlorhexidine digluconate). See Example 3-6. See instant claims 1, 3, and 26, 33, 34, 35, 42, 43. The reference also teaches using nonionic surfactants. See p. 3, lines 5-9. See instant claim 27. The reference further teaches that cationic and nonionic surfactants are also used in the amount of up to 5 % of the composition. See p. 3, lines 5 -9; instant claims 44 and 45. Adding benzoic acid, a carboxylic acid, to adjust pH of the composition is also disclosed in p. 3, lines 22-23. See instant claim 38.

The preservative of the prior art composition, formalin, is a skin-irritant, as evidenced by Poisoning & Drug Overdose, (2004, 4<sup>th</sup> ed. by Kent Olson), Lange Medical Books/McGraw-Hill, p. 575.

**Claims 1, 3, 66-70, 75-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Tanaka (US 5470563).**

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Tanaka discloses a depilatory composition comprising 40 % of strontium sulfide ( $\text{SrS}$ , salt of an aqueous divalent strontium cation) and polyoxyalkylene-modified organopolysiloxane in water. See Example 5-1; instant claims 66 and 68. Claim 69 is also met because strontium sulfide acts as a depilatory agent.

Also disclosed is a dilatory lotion comprising calcium thioglycolate (non-strontium active agent for removal of hair) and 6 % of strontium hydroxide ( $\text{Sr}(\text{OH})_2$ ). See Example 5-; instant claims 1, 3, 66-70, 75-77.

As for Claim 75, the phrase "for effective removal of hair with reduced skin irritation" is directed to the intended use or purpose of the composition, and does not limit the structure of the composition itself. Thus, no patentable weight is given to this phrase. See MPEP § 2111.02.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 71-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka as applied to claims 1, 3, 66, 68, 75-77 as above, and further in view of Bristow.**

While Takana fails to teach acidic anion species, examiner takes the position that varying different mineral acids to produce strontium salts is well within the skill of the art, absent evidence of unexpected results.

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Bristow teaches that water-soluble ionic strontium salts for pharmaceutical use include anions such as chloride, lactate, acetate, bromide, iodide, nitrate, and salicylate. See p. 2, lines 33-38.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the strontium salts of Tanaka by substituting the salts with other water-soluble strontium compounds as motivated by Bristow since both references are directed to the use of strontium salts in pharmaceutical compositions and Bristow teaches pharmaceutically acceptable salt form of strontium. The skilled artisan would have had a reasonable expectation of successfully producing a composition with similar efficacy.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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**Claims 1, 3, 38-40, 66-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 34, 43, and 54 of U.S. Patent No. 5,716,625.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising an irritant ingredient and an aqueous-soluble divalent strontium cation in overlapping concentration (57 mM-1598mM, presently claimed) in a topically suitable vehicle. See '625 patent, claims 1 and 10-21; instant claims 1, 38-40. The '625 patent also claims a method of using the presently claimed composition.

**Claims 1, 3, 26, 27, 33, 34, 38-40, 66-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 21-22, 24-26, 31-33, 35-40, 60, 61, 79, and 81 of U.S. Patent No. 5,804,203.**

The claims of the '203 patent and the present application are directed to a composition comprising an irritant ingredient and an aqueous-soluble divalent strontium cation in overlapping concentration in a topically suitable vehicle. The type of irritant ingredients claimed in the present claims 38-40 are within the scope of claims 1 and 21-22, 35-37, 60, and 61 of the '625 patent. The surfactants, emulsifiers, and the additive ingredients of instant claims 26, 27, 33, 34, are also recited in claims 24, 25, 31, 32, 38-41 of the patent. The '203 patent also claims a method of using presently claimed composition.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims have limitations that overlap with each other.

**Claims 1, 3, 38-40, 66-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 10-22, 33, 43, 70-75, 82 of U.S. Patent No. 5,958,436.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising an irritant ingredient and an aqueous-soluble divalent strontium cation in overlapping concentration in a topically suitable vehicle. See '436 patent, claims 1, 2, 10-22, 33, 70-75; instant claims 1, 38-40. The '436 patent also claims a method of using the presently claimed composition and a kit comprising the same. See '625, claims 43 and 82.

**Claims 1, 3, 38-40, 66-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-22, 30, 41, 44, 60, 83, 97, 98 of U.S. Patent No. 6139850.**

The claims of the '850 patent and the present application are directed to a composition comprising an irritant ingredient and an aqueous-soluble divalent strontium cation in overlapping concentration (57 mM-1598 mM, presently claimed) in a topically suitable vehicle. See '850, claims 1-4, 10-22, 30, 41, 44, 60-63, 83, 90; instant claims 1, 3, 38-40. The '850 patent also claims a method of using the presently claimed composition. See '850, claims 97 and 98.



Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims have limitations that overlap with each other.

### ***Response to Arguments***

Applicant's arguments filed August 28, 2006 have been considered but they are moot in view of new grounds of rejections.

### ***Allowable Subject Matter***

Claims 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Claims 1, 3, 26, 27, 33, 34, 36, 38, 42-45 and 66-77 are rejected.

Claims 39 and 40 are objected to.

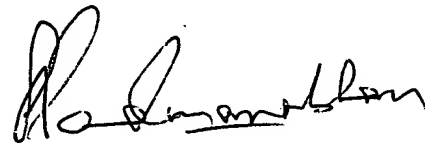
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval<sup>®</sup> (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina C. Yu  
Patent Examiner



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**



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